

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
BRYAN H. DAVIDSON
NIXON & VANDERHYE P.C.
901 NORTH GLEBE ROAD
ARLINGTON, VA 22203

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

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| Applicant's or agent's file reference 1729-35 | | Date of mailing (day/month/year) 23 JAN 2007 |
| International application No. PCT/US05/01138 | | FOR FURTHER ACTION See paragraph 2 below |
| International filing date (day/month/year) 13 January 2005 (13.01.2005) | Priority date (day/month/year) 13 January 2004 (13.01.2004) | |
| International Patent Classification (IPC) or both national classification and IPC IPC: A61F 2/02(2006.01) A61F 2/02(2006.01) USPC: 424/423 | | |
| Applicant ROYER BIOMEDICAL, INC. | | |

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application


2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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| Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201 | Date of completion of this opinion 21 December 2006 (21.12.2006) | Authorized officer  Carlos A. Azpuru Telephone No. 703-308-1235 |
|--|---|---|

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US05/01138

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 64.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/01138

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>1-39</u> | YES |
| | Claims <u>NONE</u> | NO |
| Inventive step (IS) | Claims <u>1-39</u> | YES |
| | Claims <u>NONE</u> | NO |
| Industrial applicability (IA) | Claims <u>1-39</u> | YES |
| | Claims <u>NONE</u> | NO |

2. Citations and explanations:

Claims 1-39 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the instantly claimed composition comprising an inorganic salt, and organic polymer and a non-aqueous solvent which may be combined to form an injectable used in the treatment of various diseases when combined with a bioactive.

Claims 1-39 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/01138

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

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| Novelty (N) | Claims <u>1-39</u> | YES |
| | Claims <u>NONE</u> | NO |
| Inventive step (IS) | Claims <u>1-39</u> | YES |
| | Claims <u>NONE</u> | NO |
| Industrial applicability (IA) | Claims <u>1-39</u> | YES |
| | Claims <u>NONE</u> | NO |

2. Citations and explanations:

Claims 1-39 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the instantly claimed composition comprising an inorganic salt, and organic polymer and a non-aqueous solvent which may be combined to form an injectable used in the treatment of various diseases when combined with a bioactive.

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